

**Amendments to the Claims:**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

Claims 1-43 (canceled)

44. (new) An improved method for the preparation of montelukast acid in pure form or a sodium salt thereof in amorphous form, which comprises:

- (a) generating the dilithium dianion of 1-(mercaptomethyl)cyclopropane acetic acid, (IX) by reacting with alkyl lithium,
- (b) coupling the said dianion with wet mesylate of formula (VIII) to obtain montelukast acid (VI) in crude form,
- (c) obtaining dicyclohexylamine (DCHA) salt (X) in crude form by adding DCHA to crude acid obtained in the above step (b), and
- (d) purifying and converting the said DCHA salt (X) in crude form, to montelukast acid in pure form, and optionally
- (e) reacting the pure montelukast acid in a polar protic solvent with a source of sodium ion followed by evaporating the solvent and triturating of the residue with non-polar water immiscible solvent to obtain amorphous montelukast sodium.

45. (new) An improved method for the preparation of montelukast acid in pure form and a sodium salt thereof in amorphous form, which comprises:

- (a) coupling the 1-(mercaptomethyl)cyclopropane acetic acid (IX) with mesylate of formula VIII in the presence of alkyl lithium to get montelukast acid (VI) in crude form,
- (b) obtaining dicyclohexylamine (DCHA) salt (X) in crude form by adding DCHA to crude acid obtained in the above step (a), and

(c) purifying and converting the said DCHA salt (X) in crude form, to montelukast acid in pure form, and optionally

(d) reacting the pure montelukast acid in a polar protic solvent with a source of sodium ion followed by evaporating the solvent and triturating of the residue with non-polar water immiscible solvent to obtain amorphous montelukast sodium.

46. (new) An improved method of claim 45, wherein the alkyl lithium used is methyl, ethyl, propyl, butyl, isobutyl or n-hexyl lithium.

47. (new) An improved method of claim 45, wherein, the mesylate is prepared by reacting corresponding diol with methane sulfonyl chloride in an inert solvent comprising toluene or acetonitrile or in an etheral solvent and in the presence of a tertiary amine preferably N-N di-iso propyl ethyl amine.

48. (new) An improved method of claim 47, wherein mesylation is carried out at a temperature ranging from  $-40$  to  $-25^{\circ}\text{C}$ .

49. (new) An improved method of claim 45, wherein the coupling is effected by (i) slow addition of a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) solution of wet mesylate (VIII) in THF to a cooled ( $-30$  to  $+05^{\circ}\text{C}$ ) stirred and mixed solutions of IX and n-butyl lithium in hexanes and THF, (ii) slow addition of n-butyl lithium in hexanes ( $-30$  to  $+35^{\circ}\text{C}$ ) to a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) stirred and mixed solutions of wet VIII and IX in THF, (iii) slow addition of cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) solution of IX to a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) stirred and mixed solutions of wet VIII and n-butyl lithium in THF and hexanes, (iv) slow addition of a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) solution of a mixture of IX and n-butyl lithium in hexanes and THF to a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) and stirred solution of wet VIII in THF, (v) slow addition of a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) solution of a mixture of VIII and IX to a cooled ( $-30$  to  $+5^{\circ}\text{C}$ ) and stirred solution of n-butyl lithium in hexanes and THF, (vi) slow addition of a cooled ( $-50$  to  $-25^{\circ}\text{C}$ ) solution of a mixture of VIII and n-butyl lithium in THF and hexanes to a

cooled (-30 to +5°C) and stirred solution of **IX** in THF, (vii) parallel and concurrent slow addition of solutions of n-butyl lithium (-30° to +35°C) in hexanes and 9 (at -30 to +35°C) in THF to a cooled (-30 to +05°C) solution of **VIII** in THF, (viii) parallel and concurrent slow addition of solution on n-butyl lithium (-30 to +35°C) in hexanes and a cooled solution (-30 to +05°C) of wet **VIII** in THF to a cooled and stirred solution (-30 to +05°C) of **IX** in THF, or (ix) parallel and concurrent slow addition of a cooled (-35 to +05°C) solution of **VIII** in THF and **IX** in THF (at +30 to +35°C) to a cooled (-30 to +05°C) and stirred solution of n-butyl lithium in hexanes and THF.

50. (new) An improved method of claim 45, wherein the DCHA used in step (b) is neat and the reaction is carried out in ethyl acetate, under stirring and the product so obtained is washed with ethyl acetate and hexane.

51. (new) An improved method of claim 45, wherein the DCHA salt is purified by washing with toluene or hexane.

52. (new) An improved method of claim 45, wherein conversion of DCHA salt to montelukast acid (**VI**) and its purification is carried out by treating the said salt with acid, and is effected at 0 to 40°C, at a pH of about 4-6 for 2 to 12 hrs preferably for 4 to 6 hrs, in presence of water miscible organic solvent wherein the acid used is organic or inorganic or mixture thereof.

53. (new) An improved method of claim 52, wherein the acid is any organic acid that is a long chain acid having  $C \cong 8$  or an inorganic acid wherein the strength of the acid used is 0.1M to 10M.

54. (new) An improved method of claim 53, wherein the organic acid is acetic acid, n-propionic acid, iso-propionic acid, n-butyric acid, or iso-butyric acid, and wherein inorganic

acid used is mineral and or halo acid like sulfuric, nitric, phosphoric, polyphosphoric, hydrochloric, hydrobromic, hydroiodic or hydrofluoric acid.

55. (new) An improved method of claim 45, wherein the water miscible solvent used is toluene, benzene, ortho and para xylene, methyl or ethyl acetate.

56. (new) An improved method of claim 45, wherein the purification is carried out by treating DCHA salt (X) with water immiscible polar solvent(s) comprising halogenated polar solvent(s) followed by recovering said polar solvent and crystallizing with non polar solvents, wherein the halogenated polar solvent(s) used is dichloromethane, 1,2-dichloroethane, or chloroform or a mixture thereof and the non polar solvent used is n-pentane, cyclopentane, cyclohexane, n-hexane, hexanes, cycloheptane, n-heptanes, heptane, diethyl ether, di-isopropyl ether, dibutyl ether, methyl tertiary butyl ether, benzene, toluene, ortho and para xylene, methyl acetate or ethyl acetate.

57. (new) An improved method of claim 56, wherein the recovery of water immiscible halogenated polar solvent is effected to 1/3<sup>rd</sup> of its volume.

58. (new) An improved method of claim 57, wherein the solvent is completely recovered.

59. (new) An improved method of claim 58, wherein the solvent used for crystallization is diethyl ether, di-isopropyl ether, methanol, ethanol, n-propanol, iso-propanol, butanol, iso-butanol, methyl tertiary butyl ether, benzene, toluene, or ortho and para xylene and the crystallization is performed at 10 to 30°C.

60. (new) An improved method of claim 56, wherein the crystallization is carried out using non-polar aliphatic and alicyclic organic solvents comprising cyclopentane, n-pentane, or higher homologues thereof when extraction is performed with a polar solvent.

61. (new) An improved method of claim 45, wherein the purification is carried out by treating DCHA salt (X) with an aqueous water miscible solvent followed by recovering the acid of formula VI with either precipitation using water or extraction with non-polar organic solvent wherein the water miscible solvent used is an alkanol selected from the group consisting of: methanol, ethanol, n-propanol, iso-propanol, n-butanol, iso-butanol, tetrahydrofuran, 1,2-dimethoxyethane, acetonitrile, dimethylformamide, dimethylacetamide and dimethylsulfoxide, and the non-polar organic solvent used is selected from the group consisting of methylene chloride, chloroform and 1, 2-dichloroethane, methyl acetate, ethyl acetate, benzene, toluene or ortho and para xylenes.

62. (new) An improved method of claim 45, wherein the polar protic solvent used in step (d) is lower aliphatic alcohol comprising methanol or ethanol and in the reaction in step (d) is effected at 5 to 50<sup>o</sup>C.

63. (new) An improved method for the preparation of montelukast sodium in amorphous form comprising:

- (a) providing montelukast acid in pure form, and
- (b) reacting the pure montelukast acid in a polar protic solvent with a source of sodium ion followed by evaporating the solvent and triturating of the residue with non-polar water immiscible solvent to obtain amorphous montelukast sodium, which is confirmed by powder X-Ray Diffraction (XRD) pattern shown in Figure-1.